UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	**MDL No. 1456** **Master File No. 01-12257-PBS** **Subcategory Case No. 06-11337**
THIS DOCUMENT RELATES TO: *State of California, ex rel. Ven-A-Care of the Florida Keys, Inc. v. Abbott Laboratories, Inc., et al.* Case No: 1:03-cv-11226-PBS	**Judge Patti B. Saris** **Magistrate Judge Marianne B. Bowler**

DEFENDANTS MYLAN INC., MYLAN PHARMACEUTICALS INC., DEY, INC., DEY, L.P. AND SANDOZ INC.'S JOINT REPLY BRIEF IN FURTHER SUPPORT OF THEIR MOTIONS FOR PARTIAL SUMMARY JUDGMENT

PRELIMINARY STATEMENT

Reading through the broad arguments in California's Opposition to Defendants' Joint Brief in Support of Summary Judgment ("Opposition Brief") about the Medi-Cal program's policies and goals concerning pharmacy reimbursement and its inability to respond quickly to information concerning providers' actual costs for prescription drugs, it is easy to forget that Defendants have moved for summary judgment as to only three discrete sets of claims. Nothing in California's sweeping arguments raises any issue of fact or otherwise precludes summary judgment on these three narrow issues. [1]

[1] The abbreviated citations herein are defined as follows: "Robben Decl." refers to the Declaration of Philip D. Robben In Support of Defendants' Motions for Partial Summary Judgment, dated Nov. 25, 2009 (Dkt. No. 6702), the Corrected Declaration of Philip D. Robben In Opposition to Plaintiff's Motion for Partial Summary Judgment, dated Dec. 21, 2009 (Dkt. No. 6799), and the Declaration of Philip D. Robben in Further Support of Defendants' Motions for Partial Summary Judgment, dated Jan. 15, 2010, and the exhibits annexed thereto; "Joint SOF" refers to the Defendants' Joint Statement of Undisputed Material Facts in Support of their Motions for Partial Summary Judgment, dated November 25, 2009 (Dkt. No. 6703); "Dey SOF" refers to the Statement of Undisputed Material Facts in Support of Dey, Inc. and Dey, L.P.'s Motion for Partial Summary Judgment, dated Nov. 25, 2009 (Dkt. No. 6695); "Joint Brief" refers to Defendants' Joint Brief in Support of their Motions for Partial Summary Judgment, dated November 25, 2009 (Dkt. No. 6710); "CA Opp." refers to Plaintiffs' Opposition to Defendants' Joint Brief in Support of their Motions for Partial Summary Judgment, dated Dec. 21, 2009 (Dkt. No. 6789); "Joint Opp." refers to Defendant's Joint Brief in Opposition to Plaintiffs' Motion for Partial Summary Judgment, dated Dec. 21,

First, Defendants have moved for summary judgment as to damages that accrued after the Ninth Circuit's decision in the case *Orthopaedic Hospital v. Belshe*, 103 F.3d 1491 (9th Cir. 1997) in January 1997. The evidence shows that following that decision – which prohibited California from reducing Medi-Cal reimbursement rates without first ensuring that the reduction would not adversely impact access to Medicaid – the alleged "overpayments" that California seeks to recover were not caused by Defendants' price reporting practices at all but were rather caused by California's own deliberate attempts to ensure sufficient access to quality care.

Second, Defendants have moved for summary judgment as to all liability for claims that accrued after August 2002. As demonstrated by evidence reaching back to the late 1970s and culminating with the publication of the Myers and Stauffer report and the filing of the first amended *qui tam* complaint, California's knowledge (as well as the knowledge throughout the industry) of the differences between compendia AWP and providers' actual acquisition cost was so complete by August 2002 that Plaintiffs cannot establish falsity, scienter, or causation under the California False Claims Act ("CFCA") as a matter of law.

Third, Defendants have moved for summary judgment as to all liability for claims reimbursed on the basis of a FUL. The evidence shows that the allegedly formulaic link between Defendants' price reporting practices and the establishment of a FUL that California alleged in its complaint simply does not exist.

California proffers two basic arguments in opposition to Defendants' motion on these three discrete sets of claims, each of which is demonstrably without merit. First, California contends that it only ever "intended" to pay providers for their actual acquisition costs and would

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2009 (Dkt. No. 6801); "Joint Resp. to CA SOF" refers to Defendants' Local Rule 56.1 Statement in Opposition to Plaintiffs' Statement of Additional Undisputed Facts in Opposition to Defendants' Motions for Partial Summary Judgment, dated Jan. 15, 2010.

have paid those prices had Defendants reported them as AWPs. Apart from some conclusory (and inadmissible) deposition testimony from some Medi-Cal officials elicited through leading questions by counsel for California, California offers not a shred of evidence to support this claim. In fact, the overwhelming evidence is to the contrary. Despite knowing that its reimbursement payments exceeded providers' acquisition costs, the evidence shows that California consistently resisted lowering its reimbursement rates, particularly after January 1997, out of concern that the reductions would adversely impact Medi-Cal beneficiaries' access to quality care, and never lowered its reimbursement rates to what it understood to be actual average costs. Indeed, in 2009, more than ten years after the original *qui tam* complaint in this action was filed, and more than three years after California intervened in this action, both the Ninth Circuit Court of Appeals and the District Court for the Central District of California enjoined California from lowering its reimbursement rate, which is still set at a discount off of compendia AWPs, because of the potential adverse impact such a reduction would have on access to care.

Second, California contends that its inaction in response to the extensive evidence in the public record documenting the difference between compendia AWP and actual acquisition costs does not constitute "approval" of Defendants' price reporting practices. This argument proceeds from two flawed assumptions and ignores the record evidence. First, it assumes California used AWP as one part of its reimbursement formula as a representation of some actual average of transaction prices, which it concededly did not. Second, it assumes that the existence of "express approval" is legally relevant to Defendants' motion, which it is not. Moreover, this argument ignores the fact that California had certain obligations to fulfill under federal and state laws and regulations, and was not "inactive" in light of the evidence summarized in Defendants'

motion. California controlled its reimbursement system and made no changes to the AWP benchmark for a number of years, despite its understanding of the differences between compendia AWP and actual acquisition cost. Further, it twice deliberately adopted revisions to its formula that continued to rely on relatively modest discounts to AWP to calculate reimbursement, but did not attempt to set that benchmark at a level to approximate average actual pharmacy acquisition costs for generic drugs. Finally, despite extensive evidence spread throughout the relevant time period and dating all the way back to the late 1970s showing that California knew that compendia AWPs exceeded acquisition costs, Defendants have only moved for summary judgment based on California's knowledge for a relatively brief period of time at the end of the relevant time period, from January 1997 on for damages and from August 2002 on for all liability. Even if there were some merit to California's argument (and there is none), alleged bureaucratic inertia can only excuse government inaction for so long; at some point California must act or accept the consequences of its chosen policies.

ARGUMENT

I. THE NINTH CIRCUIT'S DECISION IN *ORTHOPAEDIC HOSPITAL* BREAKS THE CAUSAL LINK BETWEEN DEFENDANTS' CONDUCT AND THE ALLEGED "OVERPAYMENTS"

As Defendants demonstrated in their moving papers, after the Ninth Circuit's decision in *Orthopaedic Hospital*, the causal link between Defendants' price reporting practices and California's alleged damages is broken. The evidence shows that California chose to reimburse at the various benchmarks within its program to ensure that Medi-Cal beneficiaries had adequate access to quality care. Stated differently, even if Defendants had reported AWPs consistent with California's "plain meaning" litigation position, the facts show California controlled its reimbursement formula, chose reimbursement rates that fulfilled its needs, including the need to maintain access to care and encourage the use of generic drugs to save

money, made those choices based in part on the knowledge and understanding that AWPs were in fact not actual averages of wholesale prices, and never chose to use its AWP minus benchmark to reimburse generic drugs at the average prices paid by retailers. California's arguments to the contrary are unavailing.[2]

A. California's Oversimplified "Causation" Argument Is Meritless

Despite the evidence of California's deliberate policy decisions concerning reimbursement levels after January 1997, California still contends that there is some causal link between Defendants' price reporting practices and California's "overpayments" after January 1997. California's oversimplified "causation" argument ignores that it was California, not Defendants, that controlled Medi-Cal's pharmacy reimbursement methodology. As California's own brief points out, Medi-Cal's use of compendia AWP as a potential basis for reimbursement was governed by statutes and regulations enacted and promulgated by California, not Defendants. (*See* CA Opp. at 10.) Moreover, these statutes and regulations do not define AWP as anything other than a price listed in a compendia and California has never offered any guidance – in a statute, regulation or otherwise – as to how AWP should be calculated. (*See* Joint Opp. at 18-19.) Thus, the notion that Defendants' price reporting practices – which California concedes were consistent with "widespread … industry practices" (*see* CA Opp. at 3) – were the "cause" of any reimbursement overpayment is untenable.

Nor has California even established that, in fact, it has suffered any damages that it could recover under the CFCA at all. Under the CFCA, California is only entitled to recover for the actual loss or harm proximately caused by the alleged violation. *See Fassberg Constr.*

[2] California's argument that damages are not a necessary element of a CFCA claim and that Defendants can be liable under the CFCA for penalties even if there is no showing of actual damages is irrelevant to this motion because Defendants only seek summary judgment on the question of liability for damages, not complete liability. Defendants disagree with Plaintiffs' position regarding penalties, but reserve their arguments on that issue because it is not before the Court.

Co. v. Hous. Auth. of City of Los Angeles, 152 Cal. App. 4th 720, 749 (Cal. Ct. App. 2007). In *Fassberg*, the defendant falsely certified that it had paid workers at the prevailing rate, pursuant to a construction contract it had entered into with the Housing Authority of the City of Los Angeles. The court rejected the Housing Authority's argument that the correct measure of damages was "the difference between the total amount paid … and the amount it would have paid if the [alleged false statements] had been truthful" and instead held the correct measure was "the amount that will compensate for all of the loss or harm proximately caused by the [false claim or false statement.]" *Id*. at 748-49. Accordingly, the court vacated the jury's damage award to Los Angeles, because, "[t]he Housing Authority received what it paid for and accepted under the terms of the contract: a completed work of construction. … The Housing Authority is not entitled to disgorgement of amounts paid under the contract as damages … because those amounts do not reflect an actual loss or harm to the Housing Authority." *Id*. at 749.[3]

The measure of "damages" that California cites to in its opposition papers – the difference between what California actually paid in ingredient cost reimbursement for the Subject Drugs, versus what California's expert, Prof. Leitzinger, purports to be the average of prices charged by defendants to wholesalers, plus an arbitrary 25 percent mark up[4] - is precisely

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[3] In a lengthy footnote, California discusses a split between federal circuits concerning whether to apply a "but for" or "proximate cause" causation analysis for claims brought under the *federal* FCA. (*See* CA Opp. at 9, n. 2.) In devoting its energies to highlighting this circuit split to the Court, California has apparently forgotten that its claims against Defendants lie under the *California* FCA, for which the controlling authority is clear that the "proximate cause" analysis is the applicable analysis. *See Fassberg*, 152 Cal. App. 4th at 749.

[4] Prof. Leitzinger specifically disclaims that the averages he calculates are the correct or accurate AWPs that Defendants should have reported to the pricing compendia. (*See* Robben Decl., Ex. 58 at 53:14-57:17; Robben Decl., Ex. 59 at 346:2-348:8.) California's Opposition, moreover, fails to explain why Prof. Leitzinger includes a 25 percent markup over his calculated quarterly average of prices received by Defendants from wholesalers in his "overpayment" calculations. The 25% markup used by Prof. Leitzinger, in fact, is at odds with California's arguments that it only intended to reimburse providers at their actual cost for a drug. (*See* CA Opp. at 4-5; Robben Decl., Ex. 58 at 206:3-207:10.)

the measure of damages the court in *Fassberg* held was improper, namely the difference between what California actually paid and what California contends it would have paid were it not for Defendants' allegedly "false" statements. California has failed to adduce any evidence that it did not get what it paid for, namely the service of having a Medi-Cal provider dispense a drug to Medi-Cal beneficiary. Given California's repeated concern that reductions in payments would jeopardize Medi-Cal beneficiaries' access to care, California got exactly what it paid for, just like the Los Angeles Housing Authority in *Fassberg*. (*See* Joint SOF at ¶¶ 33, 35, 36.)

B. ***Orthopaedic Hospital*** **and California's Subsequent Choices Concerning Reimbursement Break the Causal Link**

California does not dispute that, in the January 1997 decision in *Orthopaedic Hospital v. Belshe*, the Ninth Circuit held that Medi-Cal's reimbursement payments must be consistent with the principles of efficiency and economy, and must be sufficient to ensure that Medi-Cal beneficiaries have access to quality medical care. 103 F.3d at 1500. The Ninth Circuit further held that reimbursement rates that failed to take these four factors into account would be arbitrary, capricious, and contrary to law. *Id*. Thus, from that point on, California could not adjust its reimbursement rates without ensuring that the new rates would not impair access to quality care.

The evidence in the record demonstrates that, from 1997 on, California paid pharmacy reimbursement rates that it determined were "no higher than what is required to provide efficient and economical care, but still high enough to provide for quality care and to ensure access to services." *Id*. at 1497. For instance, in 1997, 1998, and 2000, California considered, but ultimately did not adopt, changes to Medi-Cal reimbursement methodology such as increasing the discount off of AWP or using WAC to calculate reimbursement. (*See* Joint SOF at ¶¶33, 35-36.) DHS officials acknowledged that these changes would bring prices more

in line with providers' actual costs, but expressed concerns that they would drive providers from the program and impair access to care. (*See id*.) In 2000, when given the opportunity to use AWP figures derived from actual market surveys for approximately 400 infusion, injection, and inhalation drugs, including many of the Dey Subject Drugs, California chose not to use those prices, citing concerns about access. (Dey SOF at ¶¶ 39, 40.) Once it had the Myers and Stauffer study in hand – a study that confirmed for California yet again the existence of "mega-spreads" on generic drugs including many of the Subject Drugs – it made only a modest reduction in ingredient cost reimbursement, while at the same time increasing its dispensing fee. (Joint SOF at ¶59.) Even though deeper discounts from AWP would have resulted in greater savings, DHS chose to endorse AWP minus 17 percent because it was, as one Medi-Cal official described it, "the most defensible position in the event of litigation." (Joint SOF at ¶¶ 57-58.)

In short, since January 1997, California has chosen to continue using compendia AWP to strike the appropriate balance between efficiency and economy and ensuring that Medi-Cal beneficiaries have adequate access to quality care, as required by *Orthopaedic Hospital*. Confirming the concern that deeper reductions would impair access, Medi-Cal has recently been enjoined by the Ninth Circuit and the Central District of California from implementing further reductions in Medi-Cal's pharmacy reimbursement payments because of concerns about the impact these reductions would have on access to care. (Joint Opp. at 15-16.) The Central District of California issued the injunction despite a declaration submitted by Kevin Gorospe, the Chief of the Pharmacy Policy Unit at Medi-Cal since 2000, noting the "significant profit" Medi-Cal pays providers on the ingredient cost portion of pharmacy reimbursement. (Joint SOF at ¶¶ 67-68.)

Rather than contest this evidence, California argues that the extensive public record contained in government reports and elsewhere documenting significant differences between compendia AWPs and providers' actual costs for generic drugs prior to the publication of the Myers and Stauffer report was not a "proper rate study" as defined by *Orthopaedic Hospital*, and similarly contends that the Myers and Stauffer report itself was never intended to establish the proper ingredient cost rate. Therefore, California contends, the causal link was not broken by *Orthopaedic Hospital* because, having never conducted the proper rate study that it was required to conduct by *Orthopaedic Hostpital*, it could not have lowered its rates regardless of what it understood concerning Defendants' compendia AWP. In other words, California contends that Defendants are liable for damages because California never conducted the study it needed to conduct in order to adjust its reimbursement rate. This argument is frivolous, as Defendants had absolutely no control over whether or not California could or would conduct the appropriate rate study it was obligated to conduct before revising its reimbursement rates.

Moreover, this argument misses the point. Regardless of whether the Myers and Stauffer report, or any one of the numerous other reports in the record documenting the significant differences between compendia AWPs and providers actual costs, constitutes a "proper rate study" under *Orthopaedic Hospital*, the fact remains that California was well aware by January 1997 that its ingredient cost payments for generic drugs far exceeded most providers' actual acquisition costs. Nonetheless, it chose to continue to rely on relatively modest discounts from compendia AWPs to ensure that Medi-Cal beneficiaries had adequate access to prescription drugs.

C. California's Arguments Concerning Government Inaction and a Lack of Government "Sanction" Are Meritless

Rather than contesting the evidence in the record, California attempts to cloud the issue by arguing that it never had an affirmative policy of using payments based on AWP to compensate providers for inadequate dispensing fees. Likewise, California argues that its failure to lower its reimbursement rates was a result of competing political forces and the slow moving nature of government in general, not a tacit approval of Defendants' conduct. These arguments are meritless.

California fails to point to any authority that would support holding a Defendant liable under a False Claims Act where government officials disapproved of the results of a given policy, but lacked the political will to change the policy. In fact, the law is the opposite; when the alleged "false claim" is the result of a practice that, while seemingly improper, is nonetheless a result of a deliberate government action, no false claims act liability will lie, even if government officials do not approve of the defendant's conduct. *See U.S. ex rel. Englund v. Los Angeles County*, No. CIV S-04-282 LKK/JFM, 2006 WL 3097941, at *16 (E.D. Cal. Oct. 31, 2006). In *Englund*, the defendant, Los Angeles County, used a series of intergovernmental transfers to maximize the amount of Medicaid funding it received from the federal government. *Id*. at *2-3. It would then transfer the portion of the federal funds that it did not use for Medicaid to its general fund. *Id*. at *3. The court held that, despite the fact that the federal government disapproved of the scheme, there could be no liability under the federal FCA because federal officials knew of the practice and understood it to be legal within the statutory framework governing the distribution of funds. *Id*. at *14-16. As Thomas Scully, the former administrator of CMS testified, "'everybody in Congress understood it was a total scam, but it happened to be a scam Congress authorized.'" *Id*. at *14. That one Senator described the scheme as "legal

money laundering" and that CMS had passed regulations to curb practices like the one Los Angeles engaged in were irrelevant because the federal government knew of the practice and allowed it to persist. *Id*. at *13-15. Regardless of whether Californa legislators and Medi-Cal officials may have wished that reimbursement payments closely approximated providers' actual cost, they maintained a reimbursement scheme that did not.

Moreover, the argument that bureaucratic inertia can explain California's inaction is simply not supported by the record, and ignores California's obligation to maintain its reimbursement rates at levels sufficient to ensure access to care.[5] Evidence in the record shows that California was aware for almost twenty years before the Ninth Circuit's decision in *Orthopaedic Hospital* that compendia AWP did not accurately reflect actual acquisition cost. (Joint SOF at ¶¶ 22-40.) Even though the HHS-OIG report documenting that providers could acquire generic drugs for an average of forty percent below AWP was published nine months before the *Orthopaedic Hospital* decision, it took California five years *after Orthopaedic Hospital* to consider and ultimately reject paying AWP minus 40 percent for generic drugs. (Joint SOF at ¶ 52.) The fact that the Myers and Stauffer report may have been published too late to be considered by the California legislature when it revised the pharmacy reimbursement methodology in 2002 does not change the fact that the 2002 revisions to AWP did not move to a discount level that approximated pharmacy acquisition costs. And when California adopted changes again in 2004, some two years after the publication of the Myers and Stauffer report, it knowingly adopted a rate that would continue to result in payments that significantly exceed providers' costs. (Joint SOF at ¶¶ 58-59.) Even today, some seven years after the publication of

[5] California's argument also ignores its regulatory obligation to make annual (for drugs subject to FULs) and triennial (for all other drugs) findings and assurances to CMS showing that its Medicaid expenditures satisfy the upper limits set in federal regulations. *See* 42 C.F.R. § 447.333.

the Myers and Stauffer report and the filing of the first amended *qui tam* complaint in this action, California continues to use AWP minus 17 percent as a possible reimbursement basis.

II. CALIFORNIA'S CLAIMS AFTER AUGUST 2002 REPORT ARE BARRED AS A MATTER OF LAW

As demonstrated in Defendants Joint Brief, California cannot establish liability at all after August 2002, following the receipt of a Myers and Stauffer report documenting a state-wide survey of providers' actual acquisition costs and the filing of the first amended *qui tam* complaint in this action. The first amended complaint and the Myers and Stauffer report confirmed for California what was by then common public knowledge, namely that compendia AWP for generic drugs significantly exceeded providers' acquisition costs, and further documented so-called "mega-spreads" for many of the Subject Drugs at issue in this action, some of which exceeded 1000 percent. Therefore, by August 2002 at the latest, California's knowledge of the relationship between AWP and providers' actual costs was so extensive that California cannot demonstrate falsity, scienter, or causation under the CFCA. California's arguments about the absence of some express approval misstate the applicable law, and are not sufficient to create a triable issue of fact.

A. California Misstates the Law Concerning "Government Knowledge"

California contends that, regardless of the level of detail contained in the Myers and Stauffer report concerning the spreads between compendia AWPs and actual acquisition costs for the Subject Drugs, its CFCA claims against Defendants continue for claims paid after receipt of that report because it did not "approve" of Defendants' price reporting practices. This argument is meritless. As noted in Defendants' Joint Opposition Brief, there is simply no requirement that California must expressly approve of an alleged falsity to preclude CFCA claims. *See Englund*, 2006 WL 3097941, at *12 (granting summary judgment for defendants

because "the Federal government knew what [defendant] was doing and *implicitly* approved of [defendant's] actions") (emphasis added); *United States ex rel. Burlbaw v. Orenduff*, 548 F.3d 931, 954 (10th Cir. 2008) ("[W]e conclude that neither the directness of the government-contractor communications nor their nexus to an existing contractual relationship constitute an essential predicate for the government knowledge inference."). Indeed, as discussed above, in *Englund*, a CMS official described the conduct that formed the basis of the FCA claim as "a total scam" and a United States Senator referred to the conduct as "legal money laundering." *Englund*, 2006 WL 3097941, at *14-15. The court nonetheless held that their knowledge of the alleged "scam" was sufficient to bar an FCA claim. The same is true here. California knowingly and deliberately continued using compendia AWP to pay for prescription drugs, fully aware of the difference between compendia AWPs and the average prices paid by retail pharmacies for generic prescription drugs. Inadmissible testimony from California Medi-Cal personnel that merely parrots Plaintiffs' litigation position does not make that a disputed fact. (*See* Joint Resp. to CA SOF at ¶¶13-16.)

From the false premise that government knowledge must be coupled with some sort of express approval to bar a CFCA claim, California proceeds to argue that, where the claim at issue is made pursuant to statute or regulation – as opposed to a contract between a governmental entity and a private contractor – the "approval" must be made by some affirmative act of the legislature or through the formal agency rule-making process. Since there is no requirement that the government's knowledge must be accompanied by some form of "express approval" to bar a CFCA claim, this argument fails on those grounds alone.[6]

[6] The cases that California does cite to in this section do not support this argument. *Patterson v. McLean Credit Union*, 491 U.S. 164, 175, n. 1 (1989) and *Helvering v. Hallock*, 309 U.S. 106, 121 (1940) stand for the proposition that the Supreme Court need not adhere to its own statutory precedent just because Congress failed to overturn it. *Pension Benefit Guaranty Corp. v. LTV Corp.*, 496 U.S. 633 (1990),

Moreover, California has failed to articulate what statute or regulation would need amendment to demonstrate the "approval" it contends is necessary. As discussed at length in Defendants' Joint Opposition Brief, California has never defined AWP as anything other than a price listed in a compendia, and has always been aware that it was not an average of wholesale prices for any drug, let alone those at issue in this case, and received various estimates of how AWPs compared to actual acquisition costs for generic and brand name drugs. (*See* Joint Opp. at 3-5.) On the other hand, there are other prices created for use in the Medicaid context that are clearly defined in a manner that indicates how they are to be determined, notably Average Manufacturer Price, Average Sales Price, and Wholesale Selling Price. (*See* Joint Opp. at 3-5.)

In fact, the only definition of AWP that California contends Defendants' price reporting practices ran afoul of is the "plain meaning" definition it urges the Court to adopt in its opening brief, namely that compendia AWP should have equaled an actual average of wholesale prices. However, as discussed at length in Defendants' Joint Opposition Brief, this interpretation of AWP as it is used in the statutes and regulations governing California's reimbursement methodology is simply untenable. The federal regulation that California cited to support its argument that it only ever intended to pay actual cost in fact expressly permits reimbursement

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Metropolitan Water District of Southern California v. Imperial Irrigation District, 96 Cal. Rptr. 2d 314 (Cal. Ct. App. 2000), and *Miller v. Bank of America*, 207 P.3d 531, 540 (Cal. 2009) merely stand for the proposition that when interpreting statutes or regulations, courts should not consider legislative or agency inaction, an individual legislator's understanding or an informal agency statement as dispositive of the statute's or regulation's purpose. *See also United States v. Lachman*, 387 F.3d 42, 54-55 (1st Cir. 2004) (same); *Envtl Def. v. Duke Energy Corp.*, 549 U.S. 561, 580-81 (2007) (same). None of these cases concern California or Federal FCA claims at all, much less discuss statutory or regulatory interpretation in an FCA context. The only two FCA cases cited by California, *United States ex rel. A+ Homecare, Inc. v. Medshares Management Group, Inc.*, 400 F.3d 428, 454 (6th Cir. 2005) and *United States ex rel. Kreindler & Kreindler v. United Technologies Corp.*, 985 F.2d 1148, 1156-57 (2d Cir. 1993), do not even stand for the proposition that government knowledge must be coupled with an express approval to bar an FCA claim, be it under a contractual relationship or a statutory scheme. Moreover, the passages from those cases quoted by California are not even part of the courts' holdings, but merely observations of other government knowledge cases. The *Kreindler & Kreindler* quote that California relies upon is, in fact, a quote from an *amicus curiae* brief filed by the United States. 985 F.2d at 1157.

payments that exceed acquisition cost, does not apply the estimate acquisition cost rubric to drugs subject to the separate Federal Upper Limit aggregate limits, and contemplates the use of undiscounted benchmark prices so that spreads will be paid for generic drugs to increase generic utilization. (*See* Joint Opp. at 8-10.) Moreover, by 2002, there is no evidence that any senior Medi-Cal official actually believed that AWP represented the actual net cost to a provider. (*See* Joint Opp. at 5-7.) Perhaps most tellingly, the California legislature itself adopted reimbursement methodologies based on discounted (albeit, modestly) AWPs twice after the August 2002 time period cut-off, at the same time, never expanding on or revising its definition of "AWP" as set forth in statute. (*See* Joint Brief at 10-12.) In light of this overwhelming evidence, the notion that "AWP" as it was used in the statutes enacted by the California legislature after August 2002 should reflect the final net cost to a provider, much less that Defendants ever needed some sort of statutory approval to report as AWPs something other than the final net cost to a provider, is simply untenable.

B. California's Arguments Concerning "Scienter" After August of 2002 Are Equally Unavailing

California also contends that its knowledge post-August 2002 does not bar its CFCA claims because it never communicated its approval of Defendants' price reporting practices to Defendants. This argument is meritless as well, as it stems from the same false premise that there is some requirement of express government approval. Moreover, it ignores direct evidence of direct communications between the Medi-Cal program and each of the Defendants from which Defendants could readily conclude that California did not expect compendia AWP to approximate actual acquisition costs. For instance, from 1991 to 1997, Sandoz reported its AMPs – which reflected average prices net of discounts received by Sandoz for drugs sold directly or indirectly to the retail class of trade – directly to the Medi-Cal program

on a quarterly basis. (*See* Joint Opp. at 26-28.) In 2003, a Mylan employee received a supplemental rebate worksheet from Medi-Cal that noted that AWPs for generic drugs were "inflated" and, for an example generic drug, listed an AWP and the AMP with a spread of 500 percent between the two. (*See* Joint Opp. at 28-29.) Starting in 1999, Dey began sending California letters expressly stating that its AWP did not reflect prices actually paid in the market place, and that it was Dey's practice to set an AWP once, before a product was sold, and not to subsequently change it. (*See* Joint Opp. at 29-30.) California never once attempted to contact Dey concerning these letters. (*See* Joint Opp. at 30.) Moreover, the MDL Court found that, by 2001, there was a "perfect storm" of information in the public domain concerning the existence of so-called "mega-spreads" between compendia AWP and providers' actual costs. *In re Pharm. Indus. Average Wholesale Price Litig.*, 491 F. Supp.2d 20, 41 (D. Mass. 2007).

III. CALIFORNIA'S FUL ARGUMENTS FAIL

In arguing against summary judgment on its claims for drugs reimbursed based on FULs, California does not dispute that FULs were set by CMS and not by Defendants. Nor does California dispute most of the evidence showing that CMS would often depart from the rigid formula set forth in the FUL regulations when setting FULs. The MDL Court's basis for allowing California to proceed on its FUL claims at the motion to dismiss stage was the alleged "formulaic" relationship between published prices and FULs, which the Court held created "a nexus between the alleged fraudulent reporting of prices to the compendia and the establishment of the FUL." *In re Pharm. Indus. Average Wholesale Price Litig.* (*State of California ex rel. Ven-A-Care of the Florida Keys, Inc. v. Abbott Labs., Inc.*), 478 F. Supp. 2d 164, 180 (D. Mass. 2007). Since the undisputed evidence demonstrates that CMS officials would frequently depart from the formula set forth in the regulations and instead make *ad hoc*, subjective determinations

about FULs on a drug-by-drug basis, the causal nexus between Defendants' conduct and payments made based on FUL has been broken.

Rather than dispute this point, California instead argues that a causal link between Defendants' conduct and payments based on FULs nonetheless exists by virtue of California's "lesser-of" reimbursement formula; *i.e.* that California would have always paid less than the FULs set by CMS if Defendants had reported what California's expert, Prof. Leitzinger, calculated to be the "true" AWPs.[7] However, much like California's arguments concerning causation of damages, this argument proceeds from the completely unsupported assumption that California would have always reimbursed providers at these much lower numbers. Professor Leitzinger disclaims any opinion on that topic. More importantly, as discussed above, there is simply no evidence in the record that California would ever have actually adopted these lower numbers to reimburse providers, and there is substantial evidence to the contrary. California has repeatedly considered, but ultimately rejected, alternate reimbursement bases that would have reduced payments but threatened Medi-Cal beneficiaries' access to quality care, such as deeper discounts to AWP, WACs, or DOJ AWPs. In fact, the Ninth Circuit's injunction preventing Medi-Cal from reducing pharmacy reimbursement payments would bar the use of Prof. Leitzinger's "true" AWPs today. Perhaps most tellingly is the testimony of Sue Gaston cited by California, in which she states that she departed from the formula in the regulations governing FUL "in order to ensure access while also achieving cost savings for the Medicaid program[.]"

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[7] Professor Leitzinger did not purport to calculate "true" AWPs in any event. Based on assumptions provided by the lawyers, which included an assumption that California would have changed its reimbursement formula, for his "overpayment" calculation, Prof. Leitzinger calculated, on a quarterly basis, average prices received by manufacturers from wholesalers, and added an arbitrary 25% increase. He offered no opinion as to whether such amounts should have been reported as AWPs, would have been reported by manufacturers or could have been used by California to pay ingredient cost reimbursements while ensuring access to quality care. (*See* Robben Decl., Ex. 58 at 53:14-57:17; Robben Decl., Ex. 59 at 346:2-348:8.)

(Joint Resp. to CA SOF at ¶ 69.) Given California's overarching concern with ensuring access, the notion that California would have always paid at a price below the FUL is simply untenable.[8]

Moreover, California's argument would read out of its statutes and regulations the other reimbursement benchmarks used by California to reimburse for prescription drugs. California adopted FULs and MAICs as cost savings measures to limit reimbursements to amounts below those typically generated by using the drug products AWP. It is hornbook law that statutes and regulations must be read in their full context to give effect and meaning to each portion. *See W. Pico Furniture Co. of Los Angeles v. Pac. Fin. Loans*, 2 Cal. 3d 594, 608 (Cal. 1970). In adopting FULs in 1988, for example, California reviewed actual transaction prices in the marketplace, reviewed the savings it would get from increased generic substitution, calculated and evaluated the "spread" between generic AWPs and actual acquisition costs for pharmacies in California, and decided to adopt FULs as one reimbursement measure. (Joint SOF at ¶ 26.) California cannot now read FULs and MAICs out of its statutes and regulations, nor can it walk away from the knowing policy choices it made.[9]

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[8] California attempts to counter this argument by claiming that, of the 28 million claims at issue in this action, it paid an amount less than the applicable FUL for the drug for approximately 374,000 claims, or 1.3 percent of the total number of claims at issue. California fails to offer any evidence concerning how these payments below FUL subsequently affected provider participation in the Medi-Cal program. Moreover, the fact that Medi-Cal providers may be willing to accept a reimbursement payment below a FUL one percent of the time has no bearing on how the dramatic, across-the-board reduction in reimbursement payments that would result from California's payments on Prof. Leitzinger's so-called "true" AWPs would impact provider participation.

[9] California likewise cannot ignore the federal regulations which set different aggregate upper limits for drugs subject to FULs as compared to all other drugs, or the policy statements by the federal government in connection with the adoption of the FUL aggregate limits. (*See* Joint Opp. at 8-10.)

CONCLUSION

For the foregoing reasons, and the reasons set forth in Defendants' Joint Memorandum of Law in Support of their Motions for Partial Summary Judgment, Defendants respectfully request that the Court grant their motion for partial summary judgment and dismiss California's claims for damages that accrued after January 1997, all of California's claims that accrued after August of 2002, and of California's claims that arise from reimbursement payments made on the basis of an FUL, and grant Defendants such other, further, and different relief as the Court deems to be just and proper.

Dated: January 15, 2010

Respectfully Submitted:

KELLEY DRYE & WARREN LLP

/s/Christopher C. Palermo
William A. Escobar (*pro hac vice)*
Neil Merkl (*pro hac vice*)
Christopher C. Palermo (*pro hac vice*)
Philip D. Robben (*pro hac vice*)
101 Park Avenue
New York, NY 10178
Telephone: (212) 808-7800
Facsimile: (212) 808-7897
Counsel for Mylan Inc., and Mylan Pharmaceuticals Inc.

KELLEY DRYE & WARREN LLP

/s/Sarah L. Reid
Paul F. Doyle (BBO # 133460)
William A. Escobar (*pro hac vice)*
Sarah L. Reid (*pro hac vice*)
Neil Merkl (*pro hac vice*)
Christopher C. Palermo (*pro hac vice*)
Philip D. Robben (*pro hac vice*)
101 Park Avenue
New York, NY 10178
Telephone: (212) 808-7800
Facsimile: (212) 808-7897
Counsel for Defendants Dey, Inc. and Dey, L.P.

WHITE & CASE

/s/Wayne A. Cross
Wayne A. Cross (*pro hac vice*)
Michael Gallagher (*pro hac vice*)
1155 Avenue of the Americas
New York, NY 10036
Telephone: (212) 819-8200
Facsimile: (212) 354-8113
Counsel for Sandoz Inc.

CERTIFICATE OF SERVICE

I certify that a true and correct copy of the foregoing was delivered to all counsel of record by electronic service pursuant to Paragraph 11 of Case Management Order No. 2, by causing to be sent, on January 15, 2010, a copy to LexisNexis File & Serve for posting and notification to all parties.

/s/ Sarah L. Reid
Sarah L. Reid